

PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

(Atty. Docket No.: MBHB 98-554)

In re Application of:)	Examiner:
DeVringer, <i>et al.</i>)	KISHORE, GOLLAMUDI S
)	
Application No. 09/155,605)	Art Unit: 1615
)	
Filed: September 29, 1998)	Confirmation No.: 8895
)	
For: Instant Vesicular Product)	
)	

REPLY TO EXAMINER'S ANSWER

Dear Sir:

This Reply Brief is submitted pursuant 37 C.F.R. § 41.41 in reply to the Examiner's Answer mailed December 12, 2007.

In response to the applicants' argument that not every method of removing a non-polar vehicle from the various dispersions of De Vringer would necessarily result in a powder as presently claimed, the Examiner's Answer stated that this was not persuasive because the argument is not accompanied by experimental evidence. But the applicants respectfully submit that the burden is on the Patent Office to establish that the claims are anticipated and, in the present case, that every method of removing a non-polar vehicle from the dispersion of DeVringer would lead to the presently claim powder of reversed vesicles; the applicants need not submit any data to establish patentability.

The very rejection of the claims as anticipated as well as the Examiner's Answer necessarily implies that the Office has presumed that every method of removing a non-polar vehicle from the dispersions of De Vringer would necessarily lead to the presently claimed powder of reversed vesicles each and every time. However, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original); *also* MPEP 2112. The Office has supplied no scientific evidence or reasoning based on the prior art to support such a presumption. Accordingly, the Office has failed to shift the burden to the applicants to present evidence to the contrary. MPEP 2112.

The Office also asserts that the De Vringer statement "removing the non-polar excipient(s) to obtain an instant preparation" "clearly implies that the non-polar excipient is removed contrary to applicant's arguments that no techniques for removing the vehicles cannot be applied to reverse vesicular systems without undue experimentation." But the applicants have not argued that non-polar excipient cannot be removed from a reverse vesicular system. Rather, the applicants have argued and continue to argue that not every method of removing a non-polar excipient from a reverse vesicular system will necessarily result in the presently claimed powder of reversed vesicles having the recited properties and, therefore, De Vringer cannot anticipate the claims.

On page 7 of the Examiner's Answer, in the first full paragraph, the Office states that "De Vringer teaches rotational evaporation." While this is true, a full reading of De Vringer reveals that the teaching regarding rotational evaporation is for evaporating polar organic solvents during preparation of a dispersion of reversed vesicles in a non-polar medium. Furthermore, De

Vringer clearly states that the choice of the polar solvent is essential and, among other things, should not mix with the non-polar phase (column 11, lines 15-40). Therefore De Vringer does not teach or hint at any useful method for removing the non-polar phase from a dispersion of reversed vesicles in order to obtain an instant product.

Next, on page 8, line 6, in response to the Applicant's argument that

the Office has not provided evidence or scientifically based reasoning that as of the time of filing the present invention one of ordinary skill in the art would have necessarily known of and employed a method of removing non-polar vehicles that would necessarily lead not merely to a powder, but to a powder of reversed vesicles having the properties recited in the present claims,

the Examiner's Answer states that the "preparation of liposomal powders (**reverse vesicles**) which could reconstituted into liposomes again upon the addition of a medium is known in the art." (Emphasis added.) However, liposomal powders are not reverse vesicles, and whether liposome powders could be reconstituted into liposomes is irrelevant to the present claims. Thus, the applicants respectfully submit that this argument of the applicants remains rebutted by a valid reply.

Second, on page 9, in the third sentence of the paragraph above the heading, "Rejection 3," the Examiner's Answer states,

Based on the state of the art as evident from these references and from that of **De Ringer [sic, De Vringer] (EP 562) who teaches the reverse micelles** and the removal of solvents, the preparation of powders would have been obvious to one of ordinary skill in the art with a reasonable expectation of success.

(Emphasis added.) The applicants note, however, that De Vringer teaches reversed vesicles and not reverse micelles. As explained in the Appeal Brief, the two are different entities with different properties. Thus, the applicants respectfully submit that the argument with respect to the second rejection also remains rebutted by a valid reply.

It appears to the applicants that the Office has glossed over or ignored the fundamental difference in composition and physicochemical properties among liposomes, micelles, vesicles, and each of their reversed counterparts and has assumed that techniques applicable to one form would be applicable to another. But the Office has provided no evidence of this because it cannot; the assumption is not true, as evidenced by Kunieda.

An example of this is found on page 10 of the Examiner's Answer, the Office states that the applicants' argument regarding the third rejection is not persuasive "since Blinkovsky is

concerned with **reverse** micelles and not just micelles and because the evaporation method used in both is the same, that is, rotoevaporation.” But micelles and reverse micelles are not reverse vesicles – they have different physicochemical properties. The Office has supplied no evidence that the teachings regarding reverse micelles would provide one of ordinary skill in the art with any reason to believe that methods of manipulating reverse micelles would predictably lead to the claimed powder of reversed vesicles when applied to a dispersion of De Vringer.

For all the reasons presented herein and in their Appeal Brief, and applicants respectfully submit that the present claims on appeal are patentable over the cited art and request withdrawal of the pending rejections.

Date: February 12, 2008

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Respectfully submitted,
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